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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,877	12/19/2001	William Earl Webler	5618P2977	1005

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/027,877

Applicant(s)

WEBLER, WILLIAM EARL

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 - 25 is/are pending in the application.
- 4a) Of the above claim(s) 21 - 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 18 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 - 20, drawn to an apparatus having a thermally conductive heating element, classified in class 600, subclass 549.
  - II. Claims 21 - 25, drawn to a method for determining injection depth and tissue type based on measured heat dissipation of the tissue, classified in class 600, subclass 549.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to measure blood flow.
3. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention II, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with RaulMartinez on 6/23/03 a provisional election was made without traverse to prosecute Invention I, claims 1 - 20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21 - 25 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Information Disclosure Statement***

The information disclosure statement filed 3/26/03 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

***Claim Rejections - 35 USC § 112***

6. Claims 7, 8, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In regards to claims 7 and 15, it is unclear what is meant by the phrase “approximately equal to or less than a known tissue thickness”. One of ordinary skill in the art would not be reasonably apprised of the scope of the invention based on this phrase.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 5, 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,873,835 to Hastings et al.

In regards to claims 1, 5, 6 and 10, Hastings et al. discloses applicant’s claimed invention including an elongate member in the form of a rod having dimensions suitable for insertion into a

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body (Col. 11, lines 1 – 7); at least one thermally conductive heating element comprising at least one of a wire, a film, and a thermistor material coupled to a portion of the elongate member (Col. 11, lines 7 – 9), the heating element comprising a material whose electrical resistance changes in response to a change in temperature; and an anemometry circuitry interface electrically coupled to the heating element (Abstract). Hastings et al. discloses a portion of the elongate member being electrically conductive and the anemometry circuitry interface comprising an electrically conductive lead electrically coupled to a first end of the heating element, and the elongate member electrically coupled to a second end of the heating element (Col. 11, lines 33 – 35).

10. Claims 1 – 3, 5, 6, 9, 11, 12, 14 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,431,010 to Joffe.

11. In regards to claims 1 – 3, 5, 6, 9, 11, 12, 14 and 17, Joffe discloses applicant's claimed invention including an elongate member in the form of a needle (Col. 3, lines 6 – 11) and a rod (Col. 2, lines 29 – 35) having dimensions suitable for insertion into a body; at least one thermally conductive heating element comprising at least one of a wire, a film, and a thermistor material coupled to a portion of the elongate member (Col. 3, line 64 – Col. 4, line 25), the heating element comprising a material whose electrical resistance changes in response to a change in temperature; and an anemometry circuitry interface electrically coupled to the heating element. Joffe discloses the needle having an outer diameter between 0.009 inches and 0.134 inches (Col. 3, lines 14 – 18). The anemometry circuitry interface comprises a first conductive lead electrically coupled to a first end of the heating element; and a second electrically conductive lead coupled to a second end of the heating element (Col. 2, line 30).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,431,010 to Joffe in view of U.S. Patent No. 3,470,604 to Zenick.

In reference to claims 4 and 13, Joffe discloses a hypodermic needle, but fails to disclose the needle being formed of stainless steel. However, stainless steel is well known in the medical industry for its strength, durability, ease of sterilization etc. Zenick discloses a hypodermic needle that is formed of stainless steel (Col. 1, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the hypodermic needle as disclosed by Joffe out of stainless steel as taught by Zenick in order to have a sturdy, durably and easily sterilized hypodermic needle for insertion into a patient.

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,431,010 to Joffe in view of U.S. Patent No. 5,873,835 to Hastings et al.

15. In regards to claim 18, Joffe discloses the anemometry circuitry being connected by a first conductive lead to a first end of the heating element; and a second electrically conductive lead being coupled to a second end of the heating element (Col. 2, line 30). However, Joffe fails to disclose the forming the elongate member of an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member. Hastings et al. teaches a portion of the elongate member being

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electrically conductive and the anemometry circuitry interface comprising an electrically conductive lead electrically coupled to a first end of the heating element, and the elongate member electrically coupled to a second end of the heating element (Col. 11, lines 33 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the elongate member as disclosed by Joffe to be an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member as taught by Hastings et al. in order to reduce the resistance of the electrical connections to the heating element (Col. 11, lines 33 – 35).

#### ***Allowable Subject Matter***

16. Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,207,227 to Powers and Gibbs, 1933. "A Thermoelectric Blood Flow Recorder in the Form of a Needle". Proceedings/Society for Experimental Biology and Medicine. 141 - 146.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

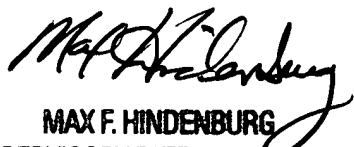
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization

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where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

JMLF  
June 30, 2003

  
**MAX F. HINDENBURG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**